

REMARKS

The present application has been reviewed in light of the Office Action mailed January 24, 2006. Claims 1-78 are currently pending, Claims 1 and 46 having been amended, and Claims 25-45 and 64-77 having been previously withdrawn. Applicants reserve the right to present previously withdrawn Claims 25-45 and 64-77 in a divisional application. Reconsideration of the present application, as amended, is respectfully requested in view of the following remarks.

Rejections under 35 U.S.C. S 103(a)

Claims 1-16, 19-24, 46-56 and 61-63 were rejected under 35 U.S.C. §103(a) as being unpatentable over Storm (U.S. Patent 4,140,130) in view of Edwards (U.S. Patent 5,964,755) and further in view of Gough et al. (U.S. Patent 5,951,547). Applicants submit that Claims 1 and 46, as amended herein, are allowable over Storm '130 in view of Edwards '755 and further in view of Gough et al. '547 because Storm '130, taken alone or in any combination with Edwards '755 and/or Gough et al. '547, does not teach or suggest either of amended independent Claims 1 and 46.

Independent Claim 1 presently recites a cooling system for use with a microwave antenna, including, *inter alia*, a cooling jacket adapted to at least partially surround a microwave antenna and defining a fluid channel around at least a portion of the microwave antenna, wherein the cooling jacket is further adapted to circulate a cooling fluid through the fluid channel such that at least a portion of the microwave antenna is in direct fluid contact with the cooling fluid and wherein the microwave antenna comprises a distal tip configured to be advanced percutaneously through tissue.

According to the present disclosure and as seen in FIGS. 4A-4E, “[a]ntenna cooling assembly 100 may generally comprise a cooling handle assembly 102 and an elongate outer jacket 108 extending from handle assembly 102. Microwave antenna 104 may be positioned within handle assembly 102 such that the radiating portion 106 of antenna 104 extends distally into outer jacket 108 towards tip 110.” (see para. [0066]). “Fluid entering handle body 112 may come into direct contact with at least a portion of the shaft of antenna 104 to allow for convective cooling of the antenna shaft to occur.” (see para. [0068]). “The cooling fluid may enter fluid channel 134 and fill the volume surrounding at least a portion of the antenna 104.” (see para. [0069]).

Storm ‘130 discloses electrode structures for radio frequency localized heating of tumor bearing tissue which are configured and adapted for **placement on the surface of the tissue** of the patient. In particular, according to Storm ‘130, the emitting surface 71 of the electrode means may comprise a flexible metallized plastic cloth to provide emitting surface 71; the metallized cloth having an electrical contact with a radio frequency terminal post 73 for transmission of electromagnetic energy to the cloth. (see col. 11, lines 43-49). Storm ‘130 further discloses cooling chamber means 74 in the form of a flexible tubing of suitable size and internal diameter **wound in spiral fashion about the post 73** and outwardly therefrom to cover the area of the metallized material 75 providing the emitting surface 71. (see col. 11, lines 50-54). Thus, Storm ‘130 fails to teach or suggest the post 73 being in direct contact with the cooling fluid, as recited in Claim 1.

Applicants respectfully submit that Storm ‘130 fails to teach or suggest either: 1) a cooling jacket adapted to at least partially surround a microwave antenna and defining a fluid channel around at least a portion of the microwave antenna; 2) at least a portion of the

microwave antenna being in direct fluid contact with the cooling fluid; and 3) wherein the microwave antenna comprises a distal tip configured to be advanced percutaneously through tissue.

Edwards '755 discloses an ablation apparatus including, *inter alia*, an expandable member 12 that is introduced into a desired body organ or lumen through an introducer sleeve 14. (see col. 4, lines 1 and 2). Applicants acknowledge the Examiner's conclusion that element 14 of Edwards '755 is a part of the microwave antenna (see page 3, lines 5-6 of the January 24, 2006 Office Action). However, Applicants respectfully disagree with the Examiners conclusion. Edwards '755 consistently refers to element 14 as an introducer sleeve and only makes mere mention that a microwave source can be coupled to the porous membrane and/or expandable member 12. (see col. 3, line 67 to col. 4, line 1, col. 4, lines 43-44, and col. 4, lines 55-57) Edwards '755 does not teach or even suggest that introducer sleeve 14 may be a part of the microwave antenna and, thus, Applicants aver that the Examiners conclusion that element 14 or introducer sleeve 14 is a part of the microwave antenna is in error.

Accordingly, since the introducer sleeve 14 of Edwards '755 is not a part of the microwave antenna, Applicants respectfully submit that Edwards '755 fails to teach or suggest the provision of a fluid channel around at least a portion of the microwave antenna, as recited in Claim 1.

Additionally, Applicants note that the Examiner has concluded that "tissue penetration includes entry into body lumens such as the cervix." (see page 3, lines 7-8 of the January 24, 2006 Office Action). Initially, Applicants respectfully submit that Claim 1, as amended in the Amendment of November 25, 2005, recites "percutaneous" and not simply "penetration" or entry

into a body lumen, as held by the Examiner. Applicants respectfully submit that the term “percutaneous,” as used and understood in the medical field, includes passage or puncturing through the skin and not simply entry into a body lumen. Thus, Applicants respectfully submit that Edwards ‘755 fails to teach or suggest a distal tip configured to be advanced percutaneously through tissue, as recited in Claim 1.

Applicants respectfully submit that Edwards ‘755 fails to remedy the deficiencies of Storm ‘130 and, thus, independent Claim 1, as amended herein, is allowable over Storm ‘130 in view of Edwards ‘755.

Gough ‘547 discloses an RF (radio frequency) ablation treatment apparatus 10 including, *inter alia*, a multiple antenna device 12 having a primary antenna 14 with a central lumen and a distal end, and a secondary antenna 16 slidably positioned within the central lumen of the primary antenna and deployable therefrom.

The Examiner holds that Gough ‘547 discloses a percutaneously advanceable microwave antenna at col. 5, lines 64-67. (see page 3, line 9 of the January 24, 2006 Office Action). Applicants respectfully submit that the holding by the Examiner that Gough ‘547 discloses a microwave antenna at col. 5, lines 64-67 is incorrect. Applicants submit that col. 5, lines 64-67 do not disclose or suggest a microwave antenna. In fact, Applicants submit that Gough ‘547 is devoid of any teaching of a microwave antenna. Accordingly, Applicants submit that Gough ‘547 may not be properly combined with any of the references of record herein to render present Claim 1 obvious.

Gough '547 fails to disclose any cooling type of cooling system, cooling jacket or a fluid channel around at least a portion of the microwave antenna and, thus, fails to remedy the deficiencies of each of Storm '130 and Edwards '755.

Therefore, Applicants respectfully submit that in view of the amendments made to Claim 1, and in view of the arguments presented above, that Claim 1 is allowable over Storm '130 in view of Edwards '755 and further in view of Gough et al. '547.

Since Claims 2-16 and 19-24 depend, directly or indirectly, from Claim 1 and contain all of the limitations of Claim 1, then for the reasons presented above regarding the patentability of Claim 1, Applicants respectfully submit that Claims 2-16 and 19-24 are also patentable over Storm '130 in view of Edwards '755 and further in view of Gough et al. '547.

Turning now to independent Claim 46, independent Claim 46 presently recites a cooling sheath system for use with a microwave antenna, including, *inter alia*, a first tubular member defining an antenna lumen therethrough, the first tubular member being adapted to extend coaxially over at least a portion of a length of the microwave antenna and to at least partially surround the microwave antenna; a second tubular member coaxially positioned about a length of the first tubular member; and a fluid channel defined between the first tubular member and the second tubular member, wherein the fluid channel is adapted to circulate a cooling fluid therethrough and envelope at least a portion of the antenna lumen and wherein the microwave antenna comprises a distal tip configured to be advanced percutaneously through tissue.

According to the present disclosure and as seen in FIGS. 13A-13C, "[cooling] sheath assembly 310 may generally comprise main tubular member 312 which defines an antenna lumen 316 therethrough. Tubular member 312 ... defines a diameter sufficient to accommodate

the shaft of a microwave antenna positioned within antenna lumen 316.” (see para. [0085]). “A coaxially positioned fluid tube 314, as seen in FIG. 13A, may be positioned around tubular member 312 and define fluid channel 322, as seen in the cross-sectional view of FIG. 13B. Fluid tube 314 may be formed as a common channel such that fluid contained therewithin envelopes or encompasses the outer surface of tubular member 312.” (see para. [0086]).

Applicants respectfully submit that none of the references of record, taken alone or in any proper combination, teach or suggest a cooling sheath system including a fluid channel defined between the first tubular member and the second tubular member, as recited in presently amended independent Claim 46.

Applicants respectfully submit that all of the arguments presented above with regard to the patentability of independent Claim 1 over Storm ‘130 in view of Edwards ‘755 and further in view of Gough et al. ‘547, apply with equal force here with regard to the patentability of Claim 46 over Storm ‘130 in view of Edwards ‘755 and further in view of Gough et al. ‘547.

Accordingly, Applicants respectfully submit that in view of the amendments made to Claim 46, and in view of the arguments presented above, that Claim 46 is allowable over Storm ‘130 in view of Edwards ‘755 and further in view of Gough et al. ‘547.

Since Claims 47-56 and 61-63 depend, directly or indirectly, from Claim 46 and contain all of the limitations of Claim 46, then for the reasons presented above regarding the patentability of Claim 46, Applicants respectfully submit that Claims 47-56 and 61-63 are also patentable over Storm ‘130 in view of Edwards ‘755 and further in view of Gough et al. ‘547.

Claims 18, 57-60, and 78 were rejected under 35 U.S.C. §103(a) as being unpatentable over Storm '130 in view of Edwards '755 and further in view of Gough et al. '547 and even further in view of Uthe (U.S. Patent 5,829,519).

Applicants respectfully submit that Claims 18, 57-60, and 78 are allowable over Storm '130 in view of Edwards '755 in view of Gough et al. '547 and even further in view of Uthe '519 since Claim 18 depends from Claim 1 and contains all of the limitations of Claim 1, and for the reasons presented above regarding the patentability of Claim 1.

Additionally, since Claims 57-60 and 78 depend, directly or indirectly, from Claim 46 and contain all of the limitations of Claim 46, for the reasons presented above regarding the patentability of Claim 46, it is respectfully submitted that Claims 57-60 and 78 are also patentable over Storm '130 in view of Edwards '755 in view of Gough et al. '547 and even further in view of Uthe '519.

Claim 17 was rejected under 35 U.S.C. §103(a) as being unpatentable over Storm '130 in view of Edwards '755 and further in view of Gough et al. '547 and even further in view of Edwards (U.S. Patent 5,281,217). Applicants submit that Claim 17 is allowable over Storm '130 in view of Edwards '755 and further in view of Gough et al. '547 and even further in view of Edwards '217 since Claim 17 depends from Claim 1 and contains all of the limitations of Claim 1, and for the reasons presented above regarding the patentability of Claim 1.

Claims 1-24, 46-63 and 78 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 25-45 and 64-77 of co-pending Application No. 11/053,987. Applicants respectfully submit that in view of the amendments to Claims 1 and 46 herein, that the provisional rejection of Claims 1-24, 46-63 and

78 in view of Claims 25-45 and 64-77 of co-pending Application No. 11/053,987 has been rendered moot and should be withdrawn.

Additionally, Applicants respectfully submit that Claims 1-24, 46-63 and 78 of the present application are directed to a cooling system or cooling sheath system and not a microwave antenna assembly as called for in Claims 25-45 and 64-77 of co-pending Application No. 11/053,987.

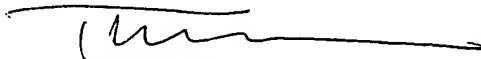
CONCLUSION

In view of the foregoing amendments and remarks, reconsideration of the application and allowance of Claims 1-24, 46-63 and 78 is earnestly solicited.

Should the Examiner believe that a telephone interview may facilitate prosecution of this application, the Examiner is respectfully requested to telephone Applicant's undersigned representative at the number indicated below.

Please charge any deficiency as well as any other fee(s) that may become due under 37 C.F.R. § 1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s), to Deposit Account No. 21-0550.

Respectfully submitted.



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